

### **REMARKS**

After entry of the amendment, claims 14-16 and 18-30 are pending, of which claims 19, 22, and 24-26 are withdrawn. Claim 17 is cancelled without disclaimer or prejudice. New claim 30 has been added and finds support *inter alia* in Examples 3 and 4 at pages 21-22. The new claim further narrows the scope of the independent claim and thus, does not present any new issues that require further consideration or search. Additionally, the total number of claims is not increased in view of the cancellation of claim 17. The claims have been amended without prejudice and disclaimer and find support *inter alia* in the original claims. The amendments to claims 14, 27, and 28 find support in original claim 10 and in the specification, for example, at page 4, lines 25-28. The amendments to claims 23 and 26 find support in the specification, for example, in Examples 3 and 4 at pages 21-22. No new matter has been added.

Applicants respectfully request entry of the above claim amendments as they are believed to put the claims in condition for allowance or, alternatively, in better form for consideration on appeal. Thus, entry under 37 CFR §1.116 is correct.

### **Rejections under 35 U.S.C. § 112, second paragraph**

The Examiner rejected claim 21 for allegedly lacking antecedent basis. In light of the amendment, the rejection is believed to be rendered moot. Withdrawal of the rejection is respectfully requested.

### **Rejections under 35 U.S.C. § 102(b)**

Claims 14-18, 20, 21, 23, 27, and 29 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Yamaguchi *et al.* (EP 773,297; hereinafter “Yamaguchi”). Applicants respectfully traverse. Claim 17 was cancelled without disclaimer or prejudice. Accordingly, the rejection as to claim 17 is rendered moot.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegall Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987). “Rejections under 35 U.S.C.S. § 102 are

proper only when the claimed subject matter is identically disclosed or described in the prior art. Thus, it is not enough that the prior art reference discloses part of the claimed invention, which an ordinary artisan might supplement to make the whole, or that it includes multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention. The prior art reference must *clearly and unequivocally* disclose the claimed invention or direct those skilled in the art to the invention without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference.” *Net MoneyIN Inc. v. VeriSign Inc.*, 545 F.3d 1359 (Fed. Cir. 2008) (holding “that unless a reference discloses within the four corners of the document not only all the limitations claimed but also *all of the limitations arranged or combined in the same way* as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102.”) (emphasis added).

The Examiner characterizes Yamaguchi as a process for producing  $\alpha$ -hydroxyamides or  $\alpha$ -hydroxy acids by reacting a microorganism having nitrilase activity with a substrate in the presence of a mixture of an aldehyde and prussic acid, *i.e.* hydrogen cyanide. Yamaguchi therefore discloses a reaction in contrast to a method for storing and/or preserving a microorganism as presently claimed.

The Examiner contends that although Yamaguchi does not expressly disclose that the nitrilase is preserved and/or stored or stabilized, Yamaguchi’s method results in said preservation, storage and stabilization because the prior art steps are the same as those claimed. Applicants strongly disagree with the Examiner characterization of the claimed invention and of Yamaguchi. The Examiner appears to misunderstand the presently claimed invention. First, the preservation, storage, and/or stabilization of the enzyme relates to a further step of the process as recited, for example, in claim 21. The present claims relate to preserving and/or storing a microorganism. In contrast, Yamaguchi teaches a reaction using a microorganism which requires the presence of all the necessary compounds for the reaction to occur. As acknowledged by the Examiner, Yamaguchi teaches reacting a microorganism with a substrate in the presence of a mixture of an aldehyde and prussic acid (synonym for hydrogen cyanide) (Office Action, page 4). Yamaguchi further teaches that certain reactants are constantly being supplied in order

to maintain their concentration within a predetermined range during the reaction, *i.e.* aldehyde,  $\alpha$ -hydroxynitrile, prussic acid (see Yamaguchi, page 3, lines 1-9, 26-27, 32-35, 40-46, 57-58; page 5, lines 13-16). Furthermore, Yanagushi discloses that their method regulates the effect of the enzyme inhibition of aldehydes by controlling the concentration of aldehyde and/or  $\alpha$ -hydroxynitrile to a predetermined range based on measuring the aldehyde concentration and/or  $\alpha$ -hydroxynitrile concentration or cyanogen concentration in the reaction mixture (see Yamaguchi, page 3, lines 53-57). Yamaguchi does not teach or suggest preserving and/or storing microorganisms in an aqueous medium and does not teach or suggest preserving and/or storing microorganisms in an aqueous medium that does not comprise any additions of cyanide compounds as presently claimed.

The Examiner alleges that because the method steps are allegedly the same, practicing the method of Yamaguchi would inherently yield the same result as those claimed. Applicants respectfully disagree.

“To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is *necessarily present* in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (emphasis added).

As already explained, Yagamuchi teaches a reaction using a microorganism, a substrate, an aldehyde, and a cyanide compound with certain reactants being constantly supplied which includes prussic acid. In contrast, the present method relates to preserving and/or storing a microorganism in an aqueous medium that does not comprise any additions of cyanide compounds. The steps of the method of Yamaguchi are clearly different than the presently claimed method steps. Contrary to the Examiner’s assertion, the practice of the method of Yamaguchi would not yield the same results as claimed. Therefore, inherency is inapplicable since the steps are not the same.

Additionally, the Examiner alleges that claims 17 and 23 are “still anticipated because the alternative that ‘or wherein the aqueous medium does not comprise any addition of said cyanide compounds’ is still met because there is no limitation as to the length of time the microorganism/aldehyde composition is free of nitrile.” (Office Action, page 4). Applicants respectfully disagree with the Examiner’s interpretation. Whether or not a time limitation is included is irrelevant since all the limitations of the claims are still not taught by Yamaguchi as required for anticipation. As explained above, Yamaguchi does not teach preserving and/or storing a microorganism in an aqueous medium which comprises at least one aldehyde and does not comprise any additions of cyanide compounds as presently claimed.

Separate consideration for new claim 30 and presently amended claim 23 is respectfully requested.

Because Yamaguchi does not teach or disclose every limitation of the claims, Yamaguchi does not anticipate the present claims. See *Gechter v. Davidson*, 116 F.3d 1454, 1460 (Fed. Cir. 1997) (“[T]o hold that a prior art reference anticipates a claim, the Board must expressly find that every limitation in the claim was identically shown in the single reference.”). Reconsideration and withdrawal of this rejection is respectfully requested.

#### **Rejections under 35 U.S.C. § 103(a)**

Claims 14-18, 20, 21, 23, and 27-29 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Yamaguchi. Applicants respectfully traverse. Claim 17 was cancelled without disclaimer or prejudice. Accordingly, the rejection as to claim 17 is rendered moot.

The examiner bears the initial burden of establishing *prima facie* obviousness. *In re Rijekaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). To support a *prima facie* conclusion of obviousness, the prior art must disclose or suggest all the limitations of the claimed invention. *In re Lowry*, 32 F.3d 1579, 1582, 32 USPQ2d 1031, 1034 (Fed. Cir. 1994).

The explanations provided above for Yamaguchi are equally applicable to this rejection and are incorporated herein in their entirety.

As in the anticipation rejection, the Examiner alleges that because the same steps are practiced, the outcome of the method of Yamaguchi would naturally result in stabilization and/or storage of the microorganism. The Examiner has added claim 28 to the obviousness rejection acknowledging that Yamaguchi does not disclose microorganisms of recombinant origin. The Examiner alleges that because recombinant microorganisms expressing nitrilase were well known, one skilled in the art would be motivated to have a recombinant microorganism express the same as substantial equivalents to their non-recombinant counterparts. Applicants respectfully disagree.

The examiner bears the initial burden of establishing *prima facie* obviousness. See *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). To support a *prima facie* conclusion of obviousness, the prior art must disclose or suggest all the limitations of the claimed invention. See *In re Lowry*, 32 F.3d 1579, 1582 (Fed. Cir. 1994).

Claims 14-16, 18, 20, 21, 27-29

As explained above, Yamaguchi teaches a **reaction** using a microorganism, a substrate, an aldehyde, and a cyanide compound with certain reactants being constantly supplied which includes prussic acid. In contrast, the present method relates to preserving and/or storing a microorganism in an aqueous medium that does not comprise any additions of cyanide compounds. The steps of the method of Yamaguchi are clearly different than the presently claimed method steps. Contrary to the Examiner's assertion, the practice of the method of Yamaguchi would not yield the same results as presently claimed because the steps of the method are different. See *In re Antonie*, 559 F.2d 618, 619-620 (CCPA 1977) (where the court reversed the Board's finding of obviousness, stating that it is the invention as a whole, and not some part of it, which must be obvious under 35 U.S.C.S. § 103 and founding that the prior art did not reveal the property which appellant discovered and, therefore, there was no basis to find obviousness); see also MPEP § 2141.02 V. Yamaguchi does not teach or suggest preserving and/or storing a microorganism let alone preserving and/or storing a microorganism in an aqueous medium that does not comprise any additions of cyanide compounds as required by the

claims. Because Yamaguchi does not disclose or suggest all the limitations of the claimed invention, a *prima facie* case of obviousness has not been established.

For at least these reasons, reconsideration and withdrawal of the rejection is respectfully requested for the independent claims and the claims dependent therefrom. *See In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988) (holding that if an independent claim is nonobvious then any claim dependent therefrom is nonobvious).

Claims 23 and 30

The explanations provided above for claims 14-16, 18, 20, 21, 27-29 are equally applicable to claims 23 and 30 and are incorporated herein in their entirety. Claims 23 and 30 additionally recite that the microorganisms are preserved and/or stored at 0°C to 22°C for at least 3.6 days.

As explained above, Yamaguchi describes a reaction, a production method with a reaction mixture for processing reactants to a product using optimal/standard temperature in the presence of all the required compounds like reactants and catalysts (microorganism) for the reaction to occur. In contrast, the present method of preserving and/or storage does not require the use of optimal reaction temperature of the microorganism or to add all the reactants. One skilled in the art reading Yamaguchi would use the standard features described for performing a standard production method. One skilled in the art reading Yamaguchi would not be motivated to preserve and/or store a microorganism in the aqueous medium as claimed and would not be motivated to preserve and/or store a microorganism in the aqueous medium as claimed at the claimed temperature for at least 3.6 days given the teaching of Yamaguchi of a reaction with no lag time and a reaction mixture with all the reactants necessary for the reaction to occur.

Yamaguchi thus does not disclose or suggest all the limitations of claims 23 and 30. Accordingly, a *prima facie* case of obviousness has also not been established for claims 23 and 30.

**CONCLUSION**

For at least the above reasons, Applicants respectfully request withdrawal of the rejections and allowance of the claims. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number given below.

Accompanying this response is a Notice of Appeal and a petition for a two-month extension of time to and including July 6, 2009, pursuant to 37 CFR § 1.7(a), to respond to the Office Action mailed February 4, 2009, with the required fee authorizations. No further fee is believed due. However, if an additional fee is due, the Director is authorized to charge our Deposit Account No. 03-2775, under Order No. 12810-00105-US from which the undersigned is authorized to draw.

Respectfully submitted,

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